



DRUG REGULATORY AUTHORITY OF PAKISTAN

[Form-1 rule 4(2), 5(1), and 6(2)]

CHECKLIST FOR GRANT OR RENEWAL OF AN ESTABLISHMENT LICENCE TO MANUFACTURE MEDICAL DEVICES.

Sr.#.	DESCRIPTION	SELECT (YES/NO/NA)
1.	Application on Form-1 (Duly signed & stamped)	
i.	New Application	
ii.	For Renewal Purpose (copy of license and last renewal attached)	
iii.	Provide the details of change of any particular of a licensed establishment (in case of any proposed change).	
2.	Proof of fee deposited: (endorsed by Statistical officer.)	
3.	Establishment Details	
i.	Provided the Establishment name, complete address, contact info.	
ii.	Provided the Type of ownership i.e. partnership, proprietorship, public & private limited etc. (Documents of land required in all cases.)	
iii.	In case of proprietorship: NTN, Online FBR Certification.	
iv.	In case of public & private limited: SECP-Form-21, Form-29, NTN.	
v.	In case of partnership: NTN, Online FBR Certification, Partnership Deed, Certificate of Registrar of firms.	
vi.	Provided the Names, photographs and copies of CNIC, of partners/proprietors/directors:	
vii.	Provided premises details, triplicate copies of LOP with dimension:	
viii.	Provided the Details of section wise equipment for manufacturing and instruments for quality control:	
4.	Detail of Qualified/ Technical Person	
i.	Provided the Name, photographs, Qualification, copies of CNIC, Degrees, experience certificate(s) and appointment letter of production in-charge for supervising manufacturing/ production department.	
ii.	Provided the Name, photographs, Qualification, copies of CNIC, Degrees, registration certificate from concerned council (where applicable) experience certificates and appointment letter of QC in-charge for supervising QC department.	
iii.	Provided the list of other technical staff working in these departments:	
5.	Provided Details of medical devices intended to be manufactured:	
6.	Provided the DECLARATION on stamp paper as per Form-1.	
7.	Provide readable softcopy along with application in USB/CD.	